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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/517,981	03/03/2000	Julie A. Bearcroft	P01952US0	5566

37983 7590 03/19/2004

SMITH & NEPHEW, INC.  
1450 E. BROOKS ROAD  
MEMPHIS, TN 38116

EXAMINER
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PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

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DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/517,981

Applicant(s)

BEARCROFT ET AL.

Examiner

Brian E Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16, 20-22, 26, 64, 65 and 67-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16, 20-22, 26, 64, 65 and 67-80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☒ The proposed drawing correction filed on 05 December 2003 is: a) ☒ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 26.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

The declaration under 37 CFR 1.132 filed 11/24/03 is sufficient to overcome the rejection of claims 1,4,9,20,21,26,64,67,70,75-77 based upon Black. However, the prior art (Ahlers) does show that a circular cross-section is obvious in the area of bone particles. Additionally, the rejection of claims 1-4,9,10,20-22,26,64,67-70,73-78 based upon Sheppard has been overcome also. However, as stated above, it is obvious to modify the shapes of the extremities and to use a transverse circular cross-section extremity as taught by Ahlers.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 76 is rejected under 35 U.S.C. 102(b) as being anticipated by Ersek et al. (5258028). Ersek et al. disclose (Fig. 5) a shaped particle with a center portion **41** and at least four tapered extremities **42** projecting from the center portion. It can be seen the projections clearly provide for interstitial spaces between adjacent extremities and since they are rounded they inherently have a circular cross-section. The particles are used for bone tissue repair, col. 9, lines 54-60.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4,9-11,14-16,20-22,26,64,65,69,70,73-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahlers (5178201) in view of Black et al. (5676700). Ahlers discloses (Fig. 2) a shaped particle and additionally shows the particle with a plurality of the shaped particles to form an array. The shaped particle has a center portion **6** and at least six extremities **7** projecting from the center portion. The rounded extremities inherently have a circular transverse cross-section. Ahlers also discloses the particles have bilateral symmetry and the projections are the same shape and size, col. 2, lines 63-65. Ahlers additionally discloses the particles are used to permit bone ingrowth, col. 3, lines 8,9. Ahlers also discloses the particles can be made of polypropylene, col. 3, lines 16-18. The diameter of the particle can be about 6mm, col. 4, lines 16-18. However, Ahlers fails to disclose the extremities as being tapered or other intended uses for the particles. Ahlers also does not disclose bioactive glass for the particles. Black teaches (Fig. 1) a shaped particle **10** having a center portion **C** and tapered extremities **12** projecting from the center portion. Black also teaches the particle is made of materials such as ceramic or bioactive glass, col. 4, lines 14-18. Black additionally teaches the shaped particle is used for repair of bone, i.e. in diseased bone, voids in bone, col. 1, lines 30-60. Fig. 4 illustrates an array of a plurality of shaped particles. Black also teaches that the extremities are tapered to enhance meshing and interlocking of the extremities in a tight relationship, col. 3, lines 34-38. It

would have been obvious to one of ordinary skill in the art to use tapered extremities as taught by Black et al. with the particles of Ahlers such that it enables the particles to be interlocked tightly and also provide mechanical properties at the area of use.

Claims 5, 6, 12, 13, 67, 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahlers '201 in view of Black et al. '700 as applied to claim 4 and 26 above, and further in view of Chen et al. (6180606). Ahlers in view of Black et al. is explained supra. However, Ahlers as modified by Black et al. do not disclose the claimed materials for the particles or composite materials. Chen et al. teach that compositions used in periodontal repair are formed of calcium compounds, col. 2, lines 13-25. Polymers such as polylactic acid can be used for the matrix and composites can also be formed of polymer/ceramic or glass combinations, col. 3, lines 40, 41, 47-50, 60-65. It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute different ceramics and use calcium phosphate or combinations of materials such as polymer composites as taught by Chen for the particles of Ahlers as modified by Black et al. in order to enhance the osteogenic potential of the composition being used.

Claims 7, 8, 71, 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahlers '201 in view of Black et al. '700 as applied to claim 6 and 70 respectively above, and further in view of Barralet (Biomaterials, 1993). Ahlers in view of Black is explained supra. However, Ahlers as modified by Black do not disclose the ceramic as gypsum or the array to have a porosity between 40-80%. Barralet teaches that calcium sulfate or gypsum having a porosity of 60%, see Abstract. It would have been obvious

to one of ordinary skill in the art to use calcium sulfate as taught by Barralet for the shaped particles of Black in order to provide a well accepted bone filler with a good porosity for bone ingrowth.

Regarding claim 65, Ahlers in view of Black et al. do not disclose resorbable materials for the particles. It would have been an obvious matter of design choice to have a resorbable material for the shaped particle, since applicant has not disclosed that this material for the particle provides any advantage, or is used for any particular purpose, or solves any stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the ceramic or bioactive glass as taught by Ahlers in view of Black or the resorbable material of claim 65 because both materials are biocompatible and remain in the body of a sufficient time to permit bone ingrowth and provide the ability to fill the bone void.

### ***Double Patenting***

Applicant is advised that should claim 3 be found allowable, claim 78 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Applicant is advised that should claim 1 be found allowable, claim 76 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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***Response to Arguments***

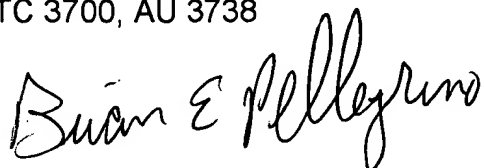
Applicant's arguments with respect to claims 1,26,73-77 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8:30am to 6pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino  
TC 3700, AU 3738

A handwritten signature in black ink that reads "Brian E. Pellegrino". The signature is written in a cursive, flowing style.